EMAUD

European Market Access University Diploma

2019-2020

*An **innovative & engaging** course*

EMAUD is run by the Academic Institute for Pharmaceutical Sciences (AIPS) and the educational arm of Market Access Society (MAS)

EMAUD's program integrates market access theory and practice throughout each step of a drug's life cycle and allows for real-world application. Students acquire the necessary skills to develop and implement strategic market access plans.

www.emaud.org

www.marketaccesssociety.org

Market Access Society

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5 modules, combining theory and practice:

- Module 1: Market Access Policy and Environment
- Module 2: Market Access Activities in Early Preparation Phase I/II
- Module 3: Market Access Activities in Phase III/Pre Launch
- Module 4: Market Access Activities in Launch/Post Launch/LCM
- Module 4bis: Health Economics and Outcome Research (optional)
- Module 5: Market Access for Vaccines, Medical Devices and Diagnostics

Interactive Modules consist of:

- Pre-reading and preparation materials
- Group workshops
- Case studies

First rate contributors and lecturers:

- Leading contributors join us from the academic world, pricing and HTA agencies, and industry organizations

Access to Annual Market Access Day:

- Students are able to access and experience an international conference centered around the latest national regulations and future challenges with respect to economic constraints and/or payers requirements.
- A debate that cannot be missed!

What does it take to achieve the EMAUD diploma?

- One of the following publications;
    - A Literature review, or review of a decision, or a landscape analysis, or case studies, or health economics projects, or pharmaco-epidemiology projects, or pricing study;

AND

- A publication submitted to a PubMed indexed scientific journal.

Support is provided to students who have little experience in writing a publication, if needed.

Training Overview

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Module 1 – 28h

Market Access Environment

Objective

- Set the scene: health environment, health policies, market access regulations across a broad range of countries. Country-specific policies are presented by Public Agency Representatives.

Activities

- Introduction to market access definition, concept, and principles
    - National stakeholders
    - Regional stakeholders
    - Local stakeholders
    - Why has market access emerged? Decision-making chain
    - Market access strategies
        - Adapting the strategy for each market access stakeholder
- Market access policies in Europe
- Market access policies outside Europe (USA, Canada, Australia, Japan, and China)
- Market access perspectives and drug development
- Key activities, outputs and benefits from Phase I to LCM: what should you do and when should you do it?

Workshop & Case study

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Module 2 – 28h

Market Access Activities in Early Preparation Phase I/II

Objectives

- Market Access landscape and strategy
- Gap Analysis and activity prioritization
- Market access planning, budgeting, and execution
- Support to development decision making
- Drivers and barriers of market access
- Incorporate market access issues in clinical development (P&R, HTA, and Market Access Plan)

Activities

- Landscape analysis
    - Desk Research
        - Disease understanding
        - Mapping
        - Literature Review (PRO, competitors, disease management, policy review, Guidelines, HTA assessment)
- Pricing
    - Payer research
    - Price anchoring studies
    - Reimbursement evaluation
- Market Access Agreements
- Early HTA advice
- Value story development and Gap Analysis

Workshop & Case study

Programme

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Module 3 – 28h

Market Access Activities in Phase III/Pre-Launch

Objectives

- Monitor Changes
- Advocacy
- Managing uncertainty
- Pricing studies
- Market access focus on specific products

Activities

- Pricing
    - P&R environment
    - Price sensitivity
    - Payer research
    - External reference pricing
    - Pricing sequence
    - Price strategy
    - P&R risk evaluation
- Building an effective advocacy strategy to support market access
- Market access specificities in emerging countries
- Market access of specific products
    - Orphan drugs
    - Oncology products
    - Cell therapies
    - Mature products
    - Value added medicine
    - Combined products (fix combination and device drugs combination)
    - Biosimilars

Workshop & Case study

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Module 4 – 28h

Market Access Activities in Launch/Post-Launch/LCM

Objectives

- Achieve P&R, HTA recommendations, and formulary inclusion at optimal prices/restrictions

Activities

- Final Pricing Strategy
- Launch
    - Negotiation guide
    - Core Value Dossier
    - Adaptation Core Value Dossier to Local Needs
    - Strategic advice
- Negotiation Skills and Strategy
- Life Cycle
    - Price database; Coordination sequence; Price Erosion
    - HEOR/Epidemiology
        - Launch
            - FDA/EMEA PRO submission dossier
            - Publication HEOR evidence (Cost-effectiveness, comparative effectiveness, clinical relevance, Phase III HEOR results)
            - Standard HTA dossier
            - Local Adaptation (Cost-effectiveness and local HTA Dossier)
            - HE studies
            - Post-hoc analyses
            - Publications
        - Life Cycle
            - IITs; real life effectiveness
            - Scientific Lobbying
            - Anticipate re-evaluation and update HTA dossier
            - Monitor New entrants/Environment
- Interaction Affiliates Region and corporate functions for successful market access

Workshop & Case study

Programme

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Module 4bis – 18h (optional)

Health economics and outcome research

Objectives

- Understand the concepts of HEOR and execute basic exercises including:
    - Develop specification of a model
    - Develop a model
    - Develop a utility instrument
    - Develop a protocol for micro-costing
    - Critical review of a model
- Morning lectures are centered around theory, while the afternoon session is dedicated to practical exercises

Activities

- Health Economics and Outcome Research
    - Conceptual Model
    - PRO Development
    - COI Studies
    - Ballpark Modelling/Value-Based Pricing
    - Early cost-effectiveness evaluation
    - Different types of models

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Module 5 – 28h

Market Access for Vaccines, Medical Devices, and Diagnostics

Objectives

- Understand the specificities of Market Access for Vaccines, Medical Devices, and Diagnostics.

Activities

- Overview of the market and strategy
- Mapping of the access process in Europe and outside Europe
- Definition, regulation, classification, certification
- HTA and NITAG
- Vaccines in emerging countries: a worldwide paradigm
- Specificities for health economics assessment and value demonstration
- Innovation and future challenges
- Value-based pricing for diagnostics and devices

Workshop & Case study

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Why a diploma in Market Access?

Market Access is a complex process. Today, it is the fourth hurdle in drug development and an inescapable reality. It has become the driver of the global income of a new product/drug. No company providing drugs or devices can expect to succeed without designing a pricing and reimbursement strategy early in the development process. The concept of Market Access requires as much knowledge as professional capabilities. It is situated at a crossroads of multiple disciplines that all form an integral part of a valid, comprehensive course. The EMAUD course, exclusively taught in English, is a pioneer degree in the field of Market Access. Speakers and contributors come from institutional organizations, the academic world, and the healthcare industry. Their presentations will cover Market Access Policies, Pricing in Europe and outside Europe, Health Economics, Health Technology Assessment, Risk Management, and Decision Sciences.

What is the objective of the EMAUD diploma?

- Gain an advanced understanding of the market access environment and principles
- Focus on the latest regulations and guidelines in Europe and outside Europe
- Draw a map of new actors: how they are becoming inescapable decision makers
- Obtain techniques and tools to implement in students' real-world business
- Develop knowledge in decision sciences
- Facilitate collaboration and contacts with experts from different organizations, public or private, who are main actors in the health industry and who confront these issues everyday
- Deliver the best practices of leading companies

Key Learnings:

- Set up a successful pricing and market strategy
- Develop, validate, and execute a market access plan
- Build a value story which optimizes market access
- Understand the strengths and pitfalls of available evidence
- Design pricing research
- Define a pricing strategy
- Anticipate the future paradigm shifts in market access

Who should attend EMAUD?

EMAUD is intended for students and professionals in the fields of life sciences and healthcare industries, including policy decision makers.

Contributors

European HTA and pricing agencies, non-governmental agencies, industry representatives, and academics.

Highlights

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ACADEMIC INSTITUTIONS

University of Aix-Marseille, France
Prof. Mondher TOUMI
Prof. Pascal AUQUIER
University of Lyon 1, France
Prof. Michel LAMURE
Tufts Center for the Study of Drug Development, USA
Prof. Joshua COHEN
Health Economics Institute, Sweden
Prof. Ulf PERSSON
University of Bocconi, Italy
Prof. Claudio JOMMI
Dr. Monica Hildegard OTTO
University of Aberdeen, Scotland
Prof. Mandy RYAN
Corvinus University of Budapest, Hungary
Prof. David DANKO
Catholic University of Sacred Heart Rome
Prof. Walter RICCIARDI
University of Tokyo, Japan
Dr. Ataru IGARASHI

GOVERNMENTAL INSTITUTIONS

HAS, France
Dr. Anne D'ANDON
Mrs. Corinne COLLIGNON
Mrs. Nadia NAOUR
NICE, UK
Mr. Mark CAMPBELL
Dr. Salyy DOSS
Ministry of Health, Poland
Mr. Jakub ADAMSKI
IQWiG, Germany
Dr. Markos DINTSIOS
Prof. Andreas GERBER
Dr. Stefan SAUERLAND
Dr. Stefan LACHIMI
G-BA, Germany
Dr. Thomas MÜLLER
Mrs. Petra NIES
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Mrs. Cristina ESPINOSA Catalan Health and Social Care Consortium, Spain
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CONSULTANCY

CPS Research, UK
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Commutateur Online
Nick HICKS
Analysis Group, Inc.
Christian FROIS
Tech2Market, France
Mr. Mathieu CYNOBER
European MS Platform, Belgium
Mr. Christoph THALHEIM
Medicines Development and Training service, France

Regular lecturers

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PHARMACEUTICAL INDUSTRY

Lundbeck
Dr. Susana MURTEIRA (Japan)
Mr. Clément FRANCOIS (USA)
Dr. Patrice VERPILLAT (France)
Mrs. Dominique MILEA (Singapore)
Amgen, France
Dr. Chantal GUILHAUME
Sanofi-Pasteur MSD, France
Mrs. Sibilia QUILICI
Sanofi Pasteur, France
Mrs. Anne TASSET-TISSEAU
Mrs. Christelle SAINT-SARDOS
GSK Biologicals
Dr. Baudouin STANDAERT
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Mr. Michiel HEMELS
Mr. Rasmus JENSEN
Genomic Health, Switzerland
Mrs. Juliette PLUN-FAVREAU
Novartis, Switzerland
Mr. Patrick MOLLON
Astellas Pharma, UK
Dr. Isaac ODEYEMI
Synovate, UK
Mr. Chris KING
Ipsen, France
Mrs. Gabrielle NAYROLES
Dr. Simon SHOHET
Eucomed, Belgium
Mr. Merlin RIETSCHEL
Abbott, Switzerland
Mrs. Kelly WONG
TEVA, The Netherlands
Mr. Adam PLICH
Air Liquide, France
Mrs. Patricia ALEGRE

Regular lecturers

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A 5 module course completed in 1-3 years based in Paris, France

The course is composed of 5 modules, each module runs for 5 consecutive days, with 1 HEOR optional module. Each module accounts for 28 hours, representing a total of 140 hours for the completion of the course. The 5 modules can be done separately and not necessarily in one year nor in any specific order (for example students may attend module 1 & 3 the first year, module 2 the second year, and module 4 & 5 during the third year). The course is validated after the submission of 2 professional theses:

- A Literature review, or review of a decision, or a landscape analysis, or case studies, or health economics projects, or pharmaco-epidemiology projects, or pricing study;

AND

- A publication that should be submitted* to a scientific journal. If needed, support will be provided to students who have little experience in writing a publication.
  **The submission will be sufficient to qualify for the diploma.*

A course exclusively given in English

Speakers and contributors come from **institutional organizations**, the **academic world** and the **healthcare industry** of Europe and outside Europe.

To apply

Please send CV and a cover letter to: application@emaud.org
Your application will be reviewed by a reading committee, and within 2 weeks you will receive a decision reached by the committee. If accepted, you will then receive your university registration file.

Contact

- **Chairman**
  Prof. Mondher Toumi, mondher.toumi@emaud.org

- **Administrative Support**
  Mrs. Małgorzata Gibek, administration@emaud.org

Description